

(K)

FILED

2013 JUL -9 P 2:02

U.S. DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA

1 CROWELL & MORING LLP  
Mark T. Jansen (CSB No. 114896)  
2 *mjansen@crowell.com*  
Jacob Z. Zambrzycki (CSB No. 289682)  
3 *jzambrzycki@crowell.com*  
275 Battery Street, 23rd Floor  
4 San Francisco, CA 94111  
Telephone: (415) 986-2800  
5 Facsimile: (415) 986-2827

6 Chiemi D. Suzuki (CSB No. 228148)  
*csuzuki@crowell.com*  
590 Madison Avenue, 20th Floor  
New York, NY 10022  
8 Telephone: (212) 223-4000  
Facsimile: (212) 223-4134

9 Attorneys for Plaintiffs  
10 PAR PHARMACEUTICAL, INC. AND  
HANDA PHARMACEUTICALS, LLC  
11

12 UNITED STATES DISTRICT COURT  
13 NORTHERN DISTRICT OF CALIFORNIA

14 PAR PHARMACEUTICAL, INC. AND  
15 HANDA PHARMACEUTICALS, LLC,

16 Plaintiffs,

17 v.

18 TAKEDA PHARMACEUTICAL CO., LTD.,  
TAKEDA PHARMACEUTICALS NORTH  
19 AMERICA, INC., TAKEDA  
PHARMACEUTICALS AMERICA, INC.,  
20 AND TAKEDA PHARMACEUTICALS  
U.S.A., INC.

21 Defendants.  
22  
23  
24  
25  
26  
27  
28

EDL

CV 13 3151

Case No. \_\_\_\_\_

COMPLAINT FOR DECLARATORY  
JUDGMENT

1 Plaintiffs Par Pharmaceutical, Inc. ("Par") and Handa Pharmaceuticals, LLC ("Handa")  
2 (collectively, "Plaintiffs"), by and through their attorneys, bring the following Complaint against  
3 Defendants Takeda Pharmaceutical Co., Ltd.; Takeda Pharmaceuticals North America, Inc.;  
4 Takeda Pharmaceuticals America, Inc.; and Takeda Pharmaceuticals U.S.A., Inc. (collectively,  
5 "Defendants") for a declaratory judgment of patent non-infringement and invalidity as follows:

6 **NATURE OF THE ACTION**

7 1. Plaintiffs seek a declaratory judgment of invalidity and/or non-infringement of  
8 U.S. Patent No. 8,461,187 ("the '187 Patent") pursuant to the Patent Laws of the United States,  
9 35 U.S.C. §§ 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.*

10 **PARTIES**

11 2. Plaintiff Par is a corporation organized under the laws of Delaware with its  
12 principal place of business at 300 Tice Boulevard, Woodcliff Lake, NJ 07677.

13 3. Plaintiff Handa is a limited liability company organized under the laws of  
14 California with its principal place of business in this district at 39465 Paseo Padre Parkway, Suite  
15 2600, Fremont, California 94538.

16 4. On information and belief, Defendant Takeda Pharmaceutical Company Limited  
17 ("TPC") is a Japanese Corporation with its principal place of business at 1-1, Doshomachi 4-  
18 chome, Chuo-ku, Osaka, Japan, and doing business in the state of California and in this district on  
19 a permanent and continuous basis.

20 5. On information and belief, Defendant Takeda Pharmaceuticals North America,  
21 Inc. ("TPNA") is a Delaware corporation with its principal place of business at One Takeda  
22 Parkway, Deerfield, IL 60015, and doing business in the state of California and in this district on  
23 a permanent and continuous basis.

24 6. On information and belief, Defendant Takeda Pharmaceuticals America, Inc.  
25 ("TPA") is a Delaware corporation, with its principal place of business at One Takeda Parkway,  
26 Deerfield, IL 60015, and doing business in the state of California and in this district on a  
27 permanent and continuous basis.

28 7. On information and belief, Defendant Takeda Pharmaceuticals U.S.A., Inc.

1 (“TP U.S.A.”) is a Delaware corporation, with its principal place of business at One Takeda  
 2 Parkway, Deerfield, IL 60015, and doing business in the state of California and in this district on  
 3 a permanent and continuous basis.

4 8. As of January 18, 2012, the name of the entity Takeda Pharmaceuticals North  
 5 America, Inc. has been changed to Takeda Pharmaceuticals U.S.A., Inc.

### 6 **JURISDICTION AND VENUE**

7 9. This Court has jurisdiction over these claims pursuant to 28 U.S.C. §§ 1331,  
 8 1338(a), 2201(a), and/or 35 U.S.C. § 271.

9 10. The Court has personal jurisdiction over Defendants, as they engage in significant  
 10 business activities in this judicial district, including selling products in this district, soliciting  
 11 business in this district, and deriving substantial revenue from this district. The Court also has  
 12 personal jurisdiction over these Defendants as they have purposefully availed themselves of the  
 13 courts of this state and this district, in particular by filing and prosecuting patent infringement  
 14 actions in this district against Par and Handa relating to Plaintiffs’ Abbreviated New Drug  
 15 Application (“ANDA”), and intent to manufacture and market a generic version of Defendants’  
 16 DEXILANT® pharmaceutical product.

17 11. Venue is proper under 28 U.S.C. §§ 1391.

### 18 **INTRADISTRICT ASSIGNMENT AND NOTICE OF RELATED PENDING CASES**

19 12. This is an Intellectual Property Action to be assigned on a district-wide basis  
 20 pursuant to Civil Local Rule 3-2(c).

21 13. Plaintiffs believe this case to be Related—within the meaning of Civil Local Rule  
 22 3-12—to Case No. 5:13-cv-01927-LHK, currently pending before the Honorable Lucy H. Koh of  
 23 the San Jose Division, and to Case No. 3:11-cv-00840-JCS, currently pending before the  
 24 Honorable Joseph C. Spero of the San Francisco Division.

### 25 **FACTUAL BACKGROUND**

26 14. TP U.S.A. (formerly known as TPNA) is the registered holder of approved New  
 27 Drug Application No. 22-287 for DEXILANT® brand dexlansoprazole capsules.

28 15. TPA sells DEXILANT® brand dexlansoprazole capsules in the United States in 30

1 mg and 60 mg dosage forms.

2       16. Handa submitted to the U.S. Food and Drug Administration (“FDA”), and Par is  
3 continuing to seek FDA approval of, ANDA No. 202-294 directed to a drug product containing  
4 dexlansoprazole. As currently amended, ANDA No. 202-294 seeks approval for Plaintiffs to  
5 engage in the commercial manufacture, use, importation, offer for sale, or sale of dexlansoprazole  
6 capsules, 60 mg (“ANDA Product”).

7       17. ANDA No. 202-294 contains bioavailability or bioequivalence data demonstrating  
8 that the ANDA Product is bioequivalent to DEXILANT®.

9       18. The ANDA Product has the same active ingredient, strength, dosage form, and  
10 route of administration as DEXILANT®, 60 mg.

11       19. The ’187 Patent, entitled “Multiple PPI Dosage Form,” issued on June 11, 2013  
12 from Application No. 11/629,016 (the “’016 Application”).

13       20. According to the U.S. Patent and Trademark Office (“USPTO”) assignment  
14 database, TP U.S.A. is the named assignee of the ’187 Patent.

15       21. On information and belief, the ’187 Patent is currently scheduled to expire on  
16 January 17, 2026.

17       22. Since TPC, TPNA (now known as TP U.S.A.), Takeda Pharmaceuticals LLC, and  
18 TPA brought a patent infringement action against Handa before the expiration of 45 days after  
19 TPC and TPNA received a notice of Paragraph IV Certifications from Handa for U.S. Patent Nos.  
20 6,462,058; 6,664,276; 6,939,971; 7,285,668; and 7,790,755—*Takeda Pharmaceutical Co., Ltd. et*  
21 *al. v. Handa Pharmaceuticals, LLC and Par Pharmaceutical, Inc.*, No. 3:11-cv-00840-JCS,  
22 currently pending in the U.S. District Court for the District of Northern California—pursuant to  
23 21 U.S.C. § 355(j)(5)(B)(iii), Par expects to receive approval from FDA to engage in the  
24 commercial manufacture, use, or sale of the ANDA Product no earlier than the expiration of the  
25 thirty-month period beginning on January 14, 2011, thus allowing Par to manufacture and market  
26 its ANDA Product in the United States.

27       23. On or about April 30, 2013, Defendants informed Plaintiffs that they consider the  
28 then-pending claims of the ’016 Application (since issued as the ’187 Patent) to be an impediment

1 to any marketing or sale of the ANDA Product.

2 24. On or about June 28, 2013, Defendants further informed Plaintiffs that they intend  
3 to move for a preliminary injunction on the '187 Patent in order to prevent Plaintiffs from  
4 marketing or selling the ANDA Product.

5 25. In view of the foregoing, an actual case and controversy exists between Plaintiffs  
6 and Defendants with respect to the '187 Patent that is within the scope of this Court's jurisdiction  
7 pursuant to 28 U.S.C. § 2201.

8 **COUNT I**

9 **DECLARATION REGARDING INVALIDITY OF THE '187 PATENT**

10 26. Plaintiffs incorporate by reference and re-allege Paragraphs 1-25 as if set forth  
11 specifically herein.

12 27. The claims of the '187 Patent are invalid for failure to satisfy the provisions of one  
13 or more of Sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

14 28. An actual and justiciable controversy exists between the parties with respect to the  
15 '187 Patent, and Plaintiffs are entitled to a declaratory judgment that the '187 Patent is invalid.

16 **COUNT II**

17 **DECLARATION REGARDING NON-INFRINGEMENT OF THE '187 PATENT**

18 29. Plaintiffs incorporate by reference and re-allege Paragraphs 1-28 as if set forth  
19 specifically herein.

20 30. The submission of ANDA No. 202-294 does not infringe any valid claim of the  
21 '187 Patent.

22 31. The commercial manufacture, use, offer for sale, sale, or importation of the ANDA  
23 Product that is the subject of ANDA No. 202-294 would not infringe any valid claim of the '187  
24 Patent.

25 32. An actual and justiciable controversy exists between the parties with respect to the  
26 '187 Patent, and Plaintiffs are entitled to a declaratory judgment that the '187 Patent is not  
27 infringed.

28

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs pray for the following relief:

A. That a judgment be entered declaring that the claims of the '187 Patent are invalid;

B. That a judgment be entered declaring that the submission of ANDA No. 202-294 does not infringe any valid claim of the '187 Patent;

C. That a judgment be entered declaring that the manufacture, use, offer for sale, sale, or importation of the ANDA Product described in ANDA No. 202-294 would not infringe any valid claim of the '187 Patent;

D. That Defendants and their agents, representatives, attorneys and those persons in active concert or participation with them who receive actual notice thereof, be preliminarily and permanently enjoined from threatening or initiating infringement litigation against Plaintiffs or any of their customers, dealers or suppliers, or any prospective or present sellers, dealers, distributors or customers of Plaintiffs, or charging any of them either orally or in writing with infringement of the '187 Patent;

E. That Plaintiffs be awarded costs, attorneys' fees and other relief, both legal and equitable, to which they may be justly entitled; and

F. That Plaintiffs be awarded such other and further relief as the Court deems just and proper.

Respectfully Submitted,

Dated: July 9, 2013

By: 

Mark T. Jansen (CSB No. 114896)

*mjansen@crowell.com*

Jacob Z. Zambrzycki (CSB No. 289682)

*jzambrzycki@crowell.com*

CROWELL & MORING LLP

275 Battery Street, 23rd Floor

San Francisco, CA 94111

Telephone: (415) 986-2800

Facsimile: (415) 986-2827

Chiemi D. Suzuki (CSB No. 228148)

*csuzuki@crowell.com*

CROWELL & MORING LLP

590 Madison Avenue, 20th Floor

New York, NY 10022

Telephone: (212) 223-4000

Facsimile: (212) 223-4134

*Attorneys for Plaintiffs*

PAR PHARMACEUTICAL, INC. AND

HANDA PHARMACEUTICALS, LLC